IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC.,	)	
	)	Redacted:
Plaintiff,	)	Public Version
v.	)	C.A. No. 19-2216-RGA
MYLAN PHARMACEUTICALS INC.,	)	[redacted]
Defendant.	)	

MEMORANDUM OF LAW IN SUPPORT OF
PAR PHARMACEUTICAL INC.'S MOTION TO INTERVENE

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INTRODUCTION

Par Pharmaceutical, Inc. ("Par") respectively moves to intervene in the above-captioned action between Plaintiff Takeda Pharmaceutical U.S.A., Inc. ("Takeda") and Defendant Mylan Pharmaceuticals Inc. ("Mylan").

Takeda manufactures an oral single active ingredient colchicine drug product, which it sells under the brand name Colcrys®. Pursuant to license and distribution agreements with Takeda, Par is the exclusive distributor of an authorized generic version of Colcrys®. Mylan's actions in launching its own generic colchicine product have already harmed and will continue to harm Par's interests as exclusive distributor of generic colchicine equivalent to Colcrys®. Par should be allowed to intervene to protect its interest in (a) Par's business and contractual relationship with Takeda concerning the exclusive distribution of generic colchicine, (b) Par's business and contractual relationships with its customers of authorized generic colchicine and (c) Par's interest in the market structure for single active ingredient colchicine established by the Par-Takeda agreements and protected by both the patents-in-suit and the agreements that resolved Takeda's litigations against Par, Mylan and other generic drug manufacturers. Par therefore respectfully asks the Court to grant its motion to intervene as a matter of right pursuant to Fed. R. Civ. P. 24(a)(2) or, in the alternative, under the Court's permissive authority pursuant to Fed. R. Civ. P. 24(b)(1)(B).

Over the past week, counsel for Par has conferred with counsel for Takeda and Mylan concerning this motion, and counsel for Par is optimistic that the parties will agree to assent on this motion and to an agreed schedule for any supplemental briefing regarding Takeda's pending motion for preliminary injunction that arises from Par's intervention. By December 17, counsel for Par had met and conferred with counsel for both Takeda and Mylan regarding Par's motion.

That day, Par also shared drafts of this brief and the accompanying proposed complaint with Takeda and Mylan at their request. The parties have continued to discuss and have exchanged proposed schedules for supplemental briefing. Due in part to counsel's travel in advance of the holidays, the parties have not yet reached agreement. Par's counsel hopes to do so shortly and will update the Court with the results of these discussions.

NATURE AND STATE OF THE PROCEEDINGS

This case is at the very earliest stages of litigation. Takeda filed its complaint against Mylan alleging breach of the license agreement and patent infringement on December 2, 2019. On December 5, 2019, Takeda filed a preliminary injunction motion seeking to stop the sale or distribution of the product described in Mylan's ANDA No. 209470 (the "Mylan ANDA Products"). Mylan's brief in opposition is due on December 20, 2019, and Takeda's reply brief is due on January 7, 2020. A hearing on the preliminary injunction has been requested but not yet scheduled. Mylan has not yet answered the complaint.

SUMMARY OF ARGUMENT

Par should be allowed to intervene pursuant to Federal Rule of Civil Procedure 24(a)(2) because Par meets all requirements for intervention by right. First, Par, as the sole authorized generic supplier of colchicine with exclusive rights from Takeda, has an interest in its existing business and contractual relations concerning generic colchicine and the associated patent rights, all of which relate to the property and transactions that are the subject of the main action. Second, Par's motion is timely, and will cause no delay to either Takeda or Mylan. Third, Par's interest in the colchicine products at issue, the contractual relations concerning the market for said drug products and the patents-in-suit may be affected or impaired, as a practical matter, by the disposition of this action. Fourth, Par's interest will not be adequately represented by an existing party in the litigation.

In the alternative, permissive intervention under Fed. R. Civ. P. 24(b)(1)(B) is appropriate because Par's claims against Mylan share a common question with the main action, specifically, whether the commercial manufacture, use, sale or offer for sale of the Mylan ANDA Products is unlawful due to infringement the patents-in-suit or violation of the 2017 Takeda-Mylan settlement agreement. Allowing Par's motion to intervene will further promote judicial economy by avoiding needlessly duplicative litigation.

STATEMENT OF FACTS

A. Prior Litigation Concerning Generic Colchicine

The seventeen patents asserted by Takeda in this litigation have been the subject of significant prior litigation in the District of Delaware. In 2013, Takeda brought the first of a series of cases against defendants seeking to market generic versions of Takeda's Colcrys® product. Par was one of these first defendants, and Par and Takeda litigated the matter from August 2013 until settlement on the eve of trial in November 2015. *Takeda Pharmaceuticals USA Inc. v. Par Pharmaceutical Companies Inc. et al* DED-1-13-cv-01524 (the "Takeda-Par Litigation"). From 2013 through 2018, Takeda pursued similar litigation against other generic drug manufacturers, including Mylan.[1] Takeda's case against Mylan was filed in October 2016 and settled in November 2017, a few months after the Court denied Mylan's motion to transfer. *Takeda Pharmaceuticals USA, Inc. v. Mylan Pharmaceuticals Inc*. DED-1-16-cv-00987. Each

[1] *See, e.g., Takeda Pharmaceuticals USA, Inc. v. Hetero Labs Limited et al* DED-1-17-cv-01020; *Takeda Pharmaceuticals USA, Inc. v. Granules Pharmaceuticals Inc.* DED-1-17-cv-01019; *Takeda Pharmaceuticals USA, Inc. v. Macleods Pharmaceuticals, Ltd. et al* DED-1-17-cv-01469; *Takeda Pharmaceuticals USA, Inc. v. Strides Pharma Global PTE Limited et al* DED-1-17-cv-01690; *Takeda Pharmaceuticals USA, Inc. v. Dr. Reddy's Laboratories, Ltd. et al* DED-1-18-cv-00101; *Takeda Pharmaceuticals USA, Inc. v. Alkem Laboratories Limited et al* DED-1-18-cv-00189; *Takeda Pharmaceuticals USA, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al* DED-1-18-cv-00464.

of Takeda's other cases similarly settled before trial.

Takeda's settlement agreements with Mylan and the other generic drug manufacturers had a common provision: that the generic drug manufacturer would not enter the market with a generic ANDA product until a date that had yet to pass as of the start of this litigation. Takeda's settlement with Par, however, included additional terms. Although Par similarly agreed to not launch its own generic colchicine version of Takeda's Colcrys® product, Par instead became the exclusive distributor of an authorized generic colchicine manufactured by Takeda. Ciarico Decl. ¶¶ 7-8.

B. Par's Exclusive Authorized Generic Colchicine

Under the agreements that ended the Takeda-Par Litigation, Par became the sole generic drug company authorized to buy Takeda's colchicine product and sell it as an authorized generic. Ciarico Decl. ¶ 8. The agreement provides for Par to purchase colchicine manufactured under Takeda's NDAs at a fixed mark-up above Takeda's cost of goods, distribute the product through Par's generic drug distribution channels, and then share the profits with Takeda according to an agreed-upon formula. Ciarico Decl. ¶ 9. This agreement allowed Par to go on the market with a colchicine product, while providing Takeda a share in the profits from distribution channels only available to a generic product. Ciarico Decl. ¶ 11.

Crucially, this mutually beneficial arrangement with a single branded drug (Takeda's Colcrys®) and a single generic version (Par's authorized generic) only functions if the market for Colcrys®-equivalent colchicine is limited to those two products. Ciarico Decl. ¶ 12. Although a drug market can maintain price stability with a single generic version of a drug on the market, multiple entrants often produce a market-wide price collapse with mass renegotiation and cancellation of supply agreements. Ciarico Decl. ¶ 12. The distribution agreement between Takeda and Par recognizes this dynamic and provides powerful incentives to ensure that the

parties preserve the two-entrant market. Most notably, if [redacted] Takeda could similarly cancel Par's right to sell the authorized generic if Par failed to perform commercially reasonable efforts to distribute the product. Ciarico Decl. ¶ 14.

Despite the challenges of generic drug distribution, Par's authorized generic has been a continuing success for the company. Par's distribution network for authorized generic colchicine (and other products) consists of a variety of entities, including nationwide distributors such as Walgreens and AmerisourceBergan as well as individual hospital and pharmacy groups. Ciarico Decl. ¶ 3. Maintaining relationships with these entities requires significant attention and resources from Par. Ciarico Decl. ¶ 4. Many of these distribution partners are aggressive in price negotiations and will use any excuse to renegotiate a more favorable rate. Ciarico Decl. ¶ 4. Despite these challenges, since Par began distribution of authorized generic colchicine in July 1, 2018, the company has booked [redacted] in net sales under the distribution agreement, contributing [redacted] in profit share to Takeda. Ciarico Decl. ¶ 10. Both companies have considered this a great success. Ciarico Decl. ¶ 10.

C. Mylan's Unlawful Interference with the Market for Generic Colchicine

Mylan's improper foray into the colchicine market has already disrupted Par's relationships with its distribution partners. Par first became aware of Mylan's activities on November 21, 2019 when one of Par's customers asked to renegotiate the terms of its supply agreement. This customer revealed to Par that Mylan had contacted it with an unsolicited bid to supply it with generic colchicine. Ciarico Decl. ¶ 15. This customer subsequently cancelled its supply agreement with Par and indicated that it would purchase colchicine tablets from Mylan instead. Ciarico Decl. ¶ 16.

Mylan placed this bid with Par's customer without any legal right to market, sell or distribute a colchicine product. Mylan's sale and marketing of a generic colchicine product infringes the patents-in-suit, and Mylan lacks authorization from Takeda to practice the patents. By unlawfully selling and/or offering to sell Mylan's a generic version of Colcrys® to Par's customers and by falsely representing (either expressly or implicitly) that Mylan has the legal right to do so, Mylan is tortiously interfering with Par's distribution agreements and engaging in unfair competition.

Mylan's wrongful actions have already damaged Par by causing Par's customers to cancel and/or seek to renegotiate their colchicine agreements. Absent prompt injunctive relief, Mylan's unauthorized sale of the Mylan ANDA Product will irreparably harm Par through further price erosion, loss of goodwill, reputational harm, and loss of business opportunities.

ARGUMENT

Under Federal Rule of Civil Procedure 24(a), "[o]n timely motion, the court must permit anyone to intervene who: … (2) claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest."

A. Par Should Be Allowed to Intervene as a Matter of Right

Rule 24(a) "is to be liberally construed in favor of intervention." *Nat'l Lab. Rev. Bd. v. Frazier*, 144 F.R.D. 650, 655 (D.N.J. 1992). To intervene as a matter of right, Par must demonstrate the following: (1) that its motion is timely; (2) that the movant has a sufficient interest in the litigation; (3) that its interest may be affected, as a practical matter, by the disposition of the actions; and (4) that its interest is not adequately represented by an existing party in the litigation. Fed. R. Civ. P. 24(a)(2); *Benjamin ex. rel. Yock v. Dep't of Pub. Welfare of*

Pa., 701 F.3d 938, 948 (3d Cir. 2012); *Mountain Top Condo. Ass'n v. Dave Stabbert Master Builder, Inc.*, 72 F.3d 361, 365-66 (3d Cir. 1995). A motion for intervention is a procedural matter not unique to patent law and therefore, regional circuit law applies. *See Stauffer v. Brooks Bros., Inc.*, 619 F.3d 1321, 1328 (Fed. Cir. 2010); *Ericsson, Inc. v. InterDigital Commc'ns Corp.*, 418 F.3d 1217, 1220-21 (Fed. Cir. 2005).

For the reasons set forth below, Par meets the requirements of Rule 24(a)(2) and should be permitted to intervene as a matter of right.

1. Par's Motion is Timely

Whether a motion to intervene is timely turns on "(1) the stage of the proceeding; (2) the prejudice that delay may cause the parties; and (3) the reason for the delay." *Mountain Top*, 72 F.3d at 369. Courts are generally reluctant to deny a motion to intervene on untimeliness grounds because a would-be intervenor may be "seriously harmed if not allowed to intervene." *Benjamin*, 701 F.3d at 949. The "mere passage of time . . . does not render an application untimely." *Mountain Top*, 72 F.3d at 369. Indeed, "timeliness is not just a function of counting days; it is determined by the totality of the circumstances." *United States v. Alcan Aluminum, Inc.*, 25 F.3d 1174, 1181 (3d Cir. 1994).

Par's motion is timely, especially as this proceeding is at the very earliest stages of litigation, there has been no delay on Par's part and there is no prospect of prejudice to any party. The complaint was filed less than three weeks ago. At the time of this motion, Mylan has yet to answer the complaint, and the pleadings remain open to amendment as a matter of course, a state that will likely persist for some time. The Court has yet to set a scheduling conference pursuant to Rule 16, and the parties have not noticed the service of any discovery. The only pending deadlines are with respect to Takeda's motion for preliminary injunction, and briefing on that motion is not due to close for several weeks. (D.I. 8.)

Par's intervention will not cause delay and will not prejudice any party. Par, if permitted to intervene promptly, would not seek to delay any deadlines in this proceeding. Par is prepared to participate in the preliminary injunction motion according to the deadlines already agreed upon by the parties. In sum, Par's intervention is timely in light of the stage of this proceeding and the absence of any delay or prejudice.

2. Par Has a Significant, Protectable Interest Related to the Property at Issue

To establish an interest sufficient for intervention, a movant must demonstrate "an interest relating to the property or transaction that is the subject of the action." Fed. R. Civ. P. 24(a)(2). The Third Circuit has explained that Rule 24 demands "flexibility when dealing with the myriad situations in which claims for intervention arise." *Kleissler v. U.S. Forrest Serv.*, 157 F.3d 964, 972 (3d Cir. 1998). The key inquiry is "whether the proposed intervenor's interest is direct or remote." *Id*. The Third Circuit has explained that "[d]ue regard for efficient conduct of the litigation requires that intervenors should have an interest that is specific to them, is capable of definition, and will be directly affected in a substantially concrete fashion by the relief sought." *Id*. "Interference with contract rights, direct economic interests, and . . . have all been deemed sufficient interests for intervention." *CSX Transp., Inc. v. City of Phila*., No. 04-CV-5023, 2005 U.S. Dist. LEXIS 14300, at *7 (E.D. Pa. July 15, 2005) (citing *Kleissler*, 157 F.3d at 972).

Here, Par's interest in the properties and transactions at issue in the main action is immediate and direct. The main action concerns the commercial manufacture, sale and offer for sale of the Mylan ANDA Products, in violation of the asserted patents. As the exclusive distributor of authorized generic colchicine, Par has a direct interest in (a) Par's business and contractual relationship with its customers, including specifically Par's authorized sales of

generic colchicine; (b) Par's business and contractual relationship with Takeda and (c) the mutually beneficial market structure established by the Par-Takeda agreements and protected by the patents-in-suit. Each of these interests is directly related to the matters at issue in the main action.

Mylan's infringing activity is already directly affecting Par's relationships with its customers. One customer has already cancelled its colchicine supply agreement, indicating that it will purchase colchicine from Mylan instead. Ciarico Decl. ¶¶ 15-16. Other customers are seeking to renegotiate prices and terms of their supply agreements. Every sale that Mylan makes to a Par customer corresponds to a lost sale for Par and an erosion of Par's rights. Ciarico Decl. ¶ 17. If Mylan's product is permitted to stay on the market, Par – like Takeda – will suffer from a declining profit margin for colchicine. Even Mylan's temporary presence on the market (for example, if Mylan is permitted to remain on the market for several months, but later loses on the merits) harms Par because price cuts to temporarily compete with Mylan cannot be easily reversed. Ciarico Decl. ¶ 18.

Mylan's infringement also directly affects Par's relationship with Takeda. If Mylan is not promptly enjoined, Mylan's entry into the market will trigger provisions in the Par-Takeda agreements that will permanently reshape that contractual relationship. Pursuant to the agreement, a failure by Takeda to police the market will trigger Par's right to launch a generic colchicine product under Par's own ANDA, ending Par's distribution of the Takeda-sourced authorized generic. Ciarico Decl. ¶ 13. Mylan's sales into the market therefore pose a risk to Par's relationship with Takeda and to the dynamics of the entire colchicine market.

Finally, Par has a direct interest in the current market structure, which is protected by the patents at issue and settlement agreement in the main case. As the exclusive distributor of

generic Colcrys®-equivalent colchicine, Par has a direct interest in the assertion of the patents in suit to block Mylan's entry into the market.

3. Disposition of this Action May Affect and Impair Par's Ability to Protect its Interest

This requirement is satisfied upon a showing that the proposed intervenor's interest "might become affected or impaired, as a practical matter, by the disposition of the action in [its] absence." *Mountain Top*, 72 F.3d at 368 (emphasis in the original); *see also* Fed. R. Civ. P. 24 advisory committee's notes to 1966 Amendment ("If an absentee would be substantially affected in a practical sense by the determination made in an action, he should, as a general rule, be entitled to intervene.").

The disposition of this action will have a substantial effect on Par's practical ability to protect its interests. In this action, the Court will decide whether to enjoin the Mylan ANDA Products, first on a preliminary basis and then as permanent matter. If the Court declines to enjoin Mylan's product the result will be immediate and significant damage to Par's various interests in the market for generic colchicine. Similarly, this Court will resolve many questions concerning the merits of Mylan's infringement of the patents in suit, an issue that is also an element of the claims asserted by Par.

In the absence of intervention, Par would retain a legal right to petition this Court for injunctive remedies that are nearly identical to the relief sought by Takeda as well as related remedies stemming from the same nucleus of operative fact. If this motion is denied, Par would likewise have the legal right to pursue its own infringement-related claims involving many of the same underlying questions of law and fact. As a matter of judicial reality, decisions adverse to Par's interests in this action will have a profound practical impact on any parallel litigation by Par, significantly impairing Par's ability to protect its interests. A delayed (and largely

duplicative) parallel proceeding with its own preliminary injunction dispute would also be an extremely inefficient use of resources for the Court and for the parties. *See Brody By & Through Sugzdinis v. Spang*, 957 F.2d 1108, 1123 (3d Cir. 1992) ("The possibility of a subsequent collateral attack does not preclude an applicant from demonstrating that his or her interests would be impaired should intervention be denied. Such a holding would reverse our policy preference which, as a matter of judicial economy, favors intervention over subsequent collateral attacks.")

4. Takeda Does Not Adequately Represent Par

Par is required to show only that its interest may be inadequately represented unless it is allowed to intervene. *See* Fed. R. Civ. P. 24(a)(2); *Mountain Top*, 72 F.3d at 368-69. The Supreme Court has recognized that "the burden of making that showing should be treated as minimal." *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972).

Par's interest in preserving its position as the sole distributor in the generic colchicine market is distinct from Takeda's interest in maximizing the combined profits from both its branded Colcrys® product and Par's authorized generic program. Although Par and Takeda are presently aligned in seeking to enjoin the sale or marketing of the Mylan ANDA Products, Takeda's position as the owner of Colcrys® and as an adverse party in Takeda-Par negotiations make Takeda an inadequate representative of Par's interests. Takeda has no direct interest in maximizing Par's benefit from the Takeda-Par agreements or any interest in protecting Par's relationship with the customers and distribution partners affected by Mylan's unauthorized venture into the market.

B. In the alternative, Par Should Be Allowed to Intervene by Permission

Federal Rule of Civil Procedure 24(b)(1) provides that "[o]n timely motion, the court may permit anyone to intervene who: … (B) has a claim or defense that shares with the main

action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B); *see also* Deutschman v. Beneficial Corp., 132 F.R.D. 359, 381-82 (D. Del. 1990). "[T]he central consideration for the exercise of discretion is whether allowing intervention will cause delay or prejudice." *Bell Atl.-Delaware, Inc. v. Global NAPS S., Inc.*, 77 F. Supp. 2d 492, 502 (D. Del. 1999); *see also* Fed. R. Civ. P. 24(b)(3). To the extent the Court finds that Par may not intervene as a matter of right, the Court should use its discretionary power to grant Par's motion to promote fairness and judicial efficiency.

Par's claims share many common questions of law and fact with the main case. Multiple claims by Par allege that Mylan's infringement of the patents asserted in the main action harm Par, giving rise to Par's claims of unfair competition and tortious interference with contractual relations, as well as patent infringement. The main action will address many legal and factual questions regarding Mylan's infringing actions and the validity of the patents at issue. Efficiency and logic demand that these questions be resolved in a single action with all interested parties, sparing the Court and the parties from needless duplicative litigation.

Par's intervention will cause no prejudice or delay. The main case is in the most preliminary stages of litigation and Par does not seek to postpone any deadlines. Par intends to cooperate and coordinate with the parties to prevent duplicative discovery and efficiently pursue the common questions at issue in the parties' claims. Nor will any parties be prejudiced by this arrangement. To the contrary, parallel duplicative litigation of the infringement issues will result in the same issues addressed on subtly different records and is far more likely to produce an unfair or prejudicial result.

CONCLUSION

For the foregoing reasons, Par respectfully requests that the Court grant its motion to

intervene, either as a matter of right under Rule 24(a)(2) or, in the alternative, permissively under Rule 24(b)(1)(B).

Dated: December 20, 2019

Respectfully submitted,

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TAB 1

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., *Plaintiff* PAR PHARMACEUTICAL, INC. *Intervenor-Plaintiff*, v. MYLAN PHARMACEUTICALS INC. *Defendants*.	)	Civil Action No. 19-2216-RGA

COMPLAINT-IN-INTERVENTION

Pursuant to Federal Rule of Civil Procedure 24, Intervenor-Plaintiff Par Pharmaceutical, Inc. ("Par"), for its complaint against Mylan Pharmaceuticals Inc. ("Mylan"), hereby alleges as follows:

THE PARTIES

Plaintiffs

1. Intervenor-Plaintiff Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par develops, manufactures, and markets pharmaceutical products in the United States.

2. Plaintiff Takeda Pharmaceuticals U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware, and its principal place of business is located at One Takeda Parkway, Deerfield, Illinois 60015.

Defendants

3. On information and belief, Defendant Mylan Pharmaceuticals, Inc. is a corporation organized and existing under the laws of West Virginia with its principal place of business at 781 Chestnut Ridge Rd., Morgantown, WV 26505.

NATURE OF THE ACTION

4. This is an action by Par against Mylan for tortious interference with contractual relations, unfair competition, and infringement of United States Patent Nos. 7,906,519 ("the '519 patent"); 7,935,731 ("the '731 patent"); 8,093,298 ("the '298 patent"); 7,964,648 ("the '648 patent"); 8,093,297 ("the '297 patent"); 7,619,004 ("the '004 patent"); 7,601,758 ("the '758 patent"); 7,820,681 ("the '681 patent"); 7,915,269 ("the '269 patent"); 7,964,647 ("the '647 patent"); 7,981,938 ("the '938 patent"); 8,093,296 ("the '296 patent"); 8,097,655 ("the '655 patent"); 8,415,395 ("the '395 patent"); 8,415,396 ("the '396 patent"); 8,440,721 ("the '721 patent"); and 8,440,722 ("the '722 patent") (collectively, "the Patents-in-Suit"). This action arises out of Mylan's launch of a generic versions of Takeda's colchicine product, Colcrys®, a product for which Par is the exclusive distributor of an authorized generic, prior to the expiration of the Patents-in-Suit.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

5. This Court has original jurisdiction over the tortious interference and unfair competition claims in this matter pursuant to 28 U.S.C. § 1332, in that the matter in controversy is between parties that are diverse and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

6. This court has subject-matter jurisdiction over this action with respect to the patent claims pursuant to 28 U.S.C. §§ 1331, 1338(a) because the claims arise under the patent laws of the United States.

Personal Jurisdiction Over Defendants

7. This Court has personal jurisdiction over Mylan because, *inter alia*, Mylan has consented to jurisdiction for the purposes of the currently pending action in this court in which Par seeks to intervene, *Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharmaceuticals, Inc.*, Civ. Act. No. 19-2216-RGA, D.I. 8.

8. On information and belief, Mylan has consented to suit in the state of Delaware by registering to do business in Delaware. Mylan is registered with the Delaware Department of State Division of Corporations as a foreign corporation and has appointed The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801, as its registered agent for the receipt of service of process. In addition, Mylan is registered with the Delaware Board of Pharmacy as an active Pharmacy – Wholesale under license number A4-0001719 and as a Distributor/Manufacturer CSR under license number DM-0007571.

9. This Court also has personal jurisdiction over Mylan because, *inter alia*, Mylan has committed, or aided, abetted, contributed to, or participated in the commission of, tortious conduct which has led to foreseeable harm and injury to Par Pharma, a Delaware corporation, in the State of Delaware, and by doing so, Mylan has purposefully directed their activities at the residents of this forum.

10. On information and belief, Mylan markets and sells generic pharmaceutical products throughout the United States, including in the State of Delaware, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to

sell or sell, generic pharmaceutical products. Mylan derives substantial revenue from goods used or consumed or services rendered in this judicial district.

11. On information and belief, Mylan has and/or will market, sell, and offer for sale its generic colchicine in the State of Delaware following FDA approval of that product.

12. On information and belief, as a result of Mylan's marketing, selling, or offering for sale of its generic colchicine in the State of Delaware, Par has and/or will lose sales of colchicine and be injured in the State of Delaware.

13. On information and belief, Mylan has previously availed itself of this forum by litigating, as a defendant, over 50 other civil actions initiated in this jurisdiction, including, for example, in *Takeda Pharmaceutical U.S.A., Inc., v. Mylan Pharmaceuticals Inc.*, C.A. 13-cv-987-SLR (D. Del. Dec. 15, 2016) (D.I. 9) (where Takeda asserted claims involving patent infringement of the same Patents-in-Suit now at issue in the present matter) and affirmatively invoked this Court's jurisdiction by asserting counterclaims in many of those cases, including, for example *UCB, Inc. v. Mylan Pharmaceuticals Inc.*, C.A. 16-cv-1214-LPS (D. Del. Sept. 16, 2013) (D.I. 11), and in *Teijin Ltd. v. Mylan Pharmaceuticals Inc.*, C.A. 13-cv-01781-SLR (D. Del. Nov. 27, 2013) (D.I. 10).

Venue

14. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and/or 1400(b).

BACKGROUND

Takeda's Branded Colchicine Drug Colcrys®

15. Takeda's branded colchicine product, Colcrys® (colchicine, USP) tablets, 0.6 mg is approved by the FDA for the prophylaxis and treatment of gout flares in adults and Familial Mediterranean Fever ("FMF") in adults and children 4 years or older.

16. Gout is an extremely painful rheumatologic condition characterized by chronic manifestations and acute flares, which are often caused by the accumulation of uric acid.

17. Colcrys® is also used to treat FMF. FMF is a rare inherited, disease characterized by abdominal pain and significant morbidity.

18. Colcrys® was the first pharmaceutical product approved by the Food and Drug Administration ("FDA") that contained colchicine as the sole active ingredient. While colchicine had been used in the United States for many years before the approval of Colcrys®, use of single-ingredient colchicine was not approved by FDA.

19. Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") currently sells, promotes, distributes, and markets its oral single-active-ingredient colchicine brand drug Colcrys® in the United States.

20. Takeda holds approved New Drug Application ("NDA") Nos. 22-351, 22-352, and 22-353 under Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a) in connection with Colcrys®.

The Patents At Issue

21. Subject to certain rights it granted to Par (discussed below), Takeda is the lawful owner of all right, title, and interest in and to the following United States patents set forth in

paragraphs 22-38 below, including the right to sue and to recover for infringement thereof, which contain one or more claims covering methods of using Colcrys®.

22. The '519 patent, titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent," a copy of which is found at D.I. 20, Exhibit C and incorporated herein by reference as though set forth in full, was duly and legally issued March 15, 2011, naming Matthew W. Davis as the inventor. The '519 patent claims, *inter alia*, a method of treating a patient in need of treatment for Familial Mediterranean Fever with colchicine by orally administering an adjusted daily dosage amount of colchicine wherein the patient is receiving concomitant administration of ritonavir.

23. The '731 patent, titled "Methods For Concomitant Administration of Colchicine and Macrolide Antibiotics," a copy of which is found at D.I. 20, Exhibit D and incorporated herein by reference as though set forth in full, was duly and legally issued May 3, 2011, naming Matthew W. Davis as the inventor. The '731 patent claims, *inter alia*, a method of using colchicine for the treatment of Familial Mediterranean Fever comprising orally administering a reduced colchicine dosage amount to a patient who is concomitantly receiving clarithromycin.

24. The '298 patent, titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," a copy of which is found at D.I. 20, Exhibit E and incorporated herein by reference as though set forth in full, was duly and legally issued January 10, 2012, naming Matthew W. Davis as the inventor. The '298 patent claims, *inter alia*, a method of using colchicine for the treatment of Familial Mediterranean Fever by orally administering a reduced dosage amount of colchicine to an adult or child who is concomitantly receiving clarithromycin.

25. The '648 patent, titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent," a copy of which is found at D.I. 20, Exhibit F and incorporated

herein by reference as though set forth in full, was duly and legally issued June 21, 2011, naming Matthew W. Davis as the inventor. The '648 patent claims, *inter alia*, a method of treating a patient with colchicine, comprising orally administering an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of ketoconazole.

26. The '297 patent, titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent," a copy of which is found at D.I. 20, Exhibit G and incorporated herein by reference as though set forth in full, was duly and legally issued January 10, 2012, naming Matthew W. Davis as the inventor. The '297 patent claims, *inter alia*, a method of treating a patient in need of treatment for gout or familial Mediterranean fever with colchicine, comprising orally administering an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of a recommended daily dosage amount of ritonavir.

27. The '004 patent, titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," a copy of which is found at D.I. 20, Exhibit H and incorporated herein by reference as though set forth in full, was duly and legally issued November 17, 2009, naming Matthew W. Davis as the inventor. The '004 patent claims, *inter alia*, a method of using colchicine for prophylactic treatment of gout flares in a human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin.

28. The '758 patent, titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics in the Treatment of Gout Flares," a copy of which is found at D.I. 20, Exhibit I and incorporated herein by reference as though set forth in full, was duly and legally issued October 13, 2009, naming Matthew W. Davis as the inventor. The '758 patent claims,

inter alia, a method of using colchicine to treat a gout flare in a human patient who is receiving concomitant administration of clarithromycin or erythromycin.

29. The '681 patent, titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent," a copy of which is found at D.I. 20, Exhibit J and incorporated herein by reference as though set forth in full, was duly and legally issued October 26, 2010, naming Matthew W. Davis as the inventor. The '681 patent claims, *inter alia*, a method of treating a patient in need of treatment for the prophylaxis of gout flares with colchicine, comprising orally administering an adjusted daily dosage amount of colchicine to a patient who is receiving concomitant administration of ritonavir.

30. The '269 patent, titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent," a copy of which is found at D.I. 20, Exhibit K and incorporated herein by reference as though set forth in full, was duly and legally issued March 29, 2011, naming Matthew W. Davis as the inventor. The '269 patent claims, *inter alia*, a method of treating a patient in need of treatment for gout flares with colchicine, comprising orally administering an adjusted daily dosage amount of colchicine wherein the patient is receiving concomitant administration of ritonavir.

31. The '647 patent, titled "Colchicine Compositions and Methods," a copy of which is found at D.I. 20, Exhibit L and incorporated herein by reference as though set forth in full, was duly and legally issued June 21, 2011, naming Matthew W. Davis as the inventor. The '647 patent claims, *inter alia*, a method of treating a patient having an acute gouty arthritis attack with colchicine.

32. The '938 patent, titled "Colchicine Compositions and Methods," a copy of which is found at D.I. 20, Exhibit M and incorporated herein by reference as though set forth in full,

was duly and legally issued July 19, 2011, naming Matthew W. Davis as the inventor. The '938 patent claims, *inter alia*, a method of treating a gout flare with colchicine in a patient undergoing colchicine prophylactic treatment of gout flares.

33. The '296 patent, titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," a copy of which is found at D.I. 20, Exhibit N and incorporated herein by reference as though set forth in full, was duly and legally issued January 10, 2012, naming Matthew W. Davis as the inventor. The '296 patent claims, *inter alia*, a method of using colchicine to treat gout flares in an adult human gout patient so as to reduce the occurrence of colchicine toxicity when the patient is receiving concomitant administration of clarithromycin.

34. The '655 patent, titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," a copy of which is found at D.I. 20, Exhibit O and incorporated herein by reference as though set forth in full, was duly and legally issued January 17, 2012, naming Matthew W. Davis as the inventor. The '655 patent claims, *inter alia*, a method of using colchicine for prophylactic treatment of gout flares in an adult human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin.

35. The '395 patent, titled "Colchicine Compositions and Methods," a copy of which is found at D.I. 20, Exhibit P and incorporated herein by reference as though set forth in full, was duly and legally issued April 9, 2013, naming Matthew W. Davis and Hengsheng Feng as inventors. The '395 patent claims, *inter alia*, a method of treating a patient having a gout flare.

36. The '396 patent, titled "Colchicine Compositions and Methods," a copy of which is found at D.I. 20, Exhibit Q and incorporated herein by reference as though set forth in full,

was duly and legally issued April 9, 2013, naming Matthew W. Davis and Hengsheng Feng as inventors. The '396 patent claims, *inter alia*, a method of treating a patient having a gout flare.

37. The '721 patent, titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent," a copy of which is found at D.I. 20, Exhibit R and incorporated herein by reference as though set forth in full, was duly and legally issued May 14, 2013, naming Matthew W. Davis as the inventor. The '721 patent claims, *inter alia*, a method of treating a patient in need of treatment for acute gout flares with colchicine, comprising orally administering an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of verapamil.

38. The '722 patent, titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent," a copy of which is found at D.I. 20, Exhibit S and incorporated herein by reference as though set forth in full, was duly and legally issued May 14, 2013, naming Matthew W. Davis as the inventor. The '722 patent claims, *inter alia*, a method of treating a patient in need of treatment for prophylaxis of gout flares with colchicine, comprising orally administering an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of verapamil.

39. The '647, '938, '395, and '396 patents are collectively referred to herein as the "Acute Gout Flare Patents."

40. The '519, '731, '298, '297, '004, '758, '681, '269, '648, '296, '655, '721, and '722 patents are collectively referred to herein as the "Drug-Drug Interaction" or "DDI Patents."

41. The FDA's official publication of approved drugs (the "Orange Book") lists the Patents-in-Suit in connection with pharmaceutical product, Colcrys®. Pursuant to 21 U.S.C. § 355(b)(1), the Patents-in-Suit are listed in the FDA's publication titled "Approved Drug

Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Colcrys®.

Prior Litigation between Takeda and Par

42. In 2013, Takeda brought the first of a series of cases against defendants seeking to market generic versions of Takeda's Colcrys® product. Par was one of these first defendants.

43. Par filed with the FDA ANDA No. 203976 under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a colchicine product that Takeda asserts is a generic copy of Colcrys® ("Par's ANDA Product") prior to the expiration of the Patents-in-Suit.

44. Takeda filed *Takeda Pharmaceuticals USA Inc. v. Par Pharmaceutical Companies Inc. et al*., DED-1-13-cv-01524, in August 2013 (the "Takeda-Par Litigation").

45. Par and Takeda litigated the matter until they reached a settlement agreement in November 2015 (discussed below) on the eve of trial.

Par's Exclusive Authorized Generic Colchicine

46. Under the agreements that ended the Takeda-Par Litigation, Par became the sole generic drug company authorized to buy Takeda's colchicine product and sell it as an authorized generic during a specified time period. The agreement provides for Par to purchase colchicine manufactured pursuant to Takeda's NDAs, distribute the product through Par's generic drug distribution channels and then share profits with Takeda according to an agreed-upon formula.

47. This mutually beneficial arrangement with a single branded drug (Takeda's Colcrys®) and a single generic version (Par's authorized generic) depends on limiting the market for colchicine to those two products. The distribution agreement between Takeda and Par recognizes this dynamic and provides incentives to ensure that Takeda will enforce its patents to

maintain market exclusivity. Par entered into this agreement, at least in part, in reliance on Takeda's commitment to patent enforcement.

48. Par's distribution network for authorized generic colchicine includes a variety of corporate partners. Par has correctly informed its distribution partners that Par is the only authorized generic version of Takeda's Colcrys® drug product.

49. Par has executed Group Purchasing Agreements or similar contracts with its distribution partners. These agreements set forth purchasing terms for lists of generic pharmaceutical products, and are subject to periodic renegotiation. Par's sales of its generic pharmaceutical products, including generic colchicine, are pursuant to these agreements.

50. In its capacity as a generic drug manufacturer, Mylan is familiar with agreements of this nature.

51. Mylan is aware, and at all relevant times was aware, that Par maintains Group Purchasing Agreements or equivalent contracts with Par's distribution partners, and that Par's authorized generic colchicine was sold to Par's distribution partners subject to agreements of this nature.

52. Mylan is aware, and at all relevant times was aware, that Par distributes its authorized generic colchicine product pursuant to one or more contractual agreements with Takeda.

Prior Litigation with Takeda and Mylan and Other Generic Drug Manufacturers

53. Mylan filed with the FDA Abbreviated New Drug Application ("ANDA") No. 209470 under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a colchicine product that Takeda asserts is a generic copy of Colcrys® ("Mylan's ANDA Product") prior to the expiration of the Patents-in-Suit.

54. Takeda brought suit against Mylan on October 24, 2016 in a case captioned *Takeda Pharmaceuticals USA, Inc. v. Mylan Pharmaceuticals Inc.*, Civ. Act. No. 16-cv-00987-RGA (D. Del.).

55. On information and belief, Takeda and Mylan stipulated to dismissal of this suit in November 2017 pursuant to a settlement agreement in which Mylan agreed not to enter the market with a generic colchicine product until a specified date that had not yet been reached as of the initiation of this litigation.

56. On information and belief, Mylan knew at the time it entered into its settlement agreement that Takeda could and might authorize a generic pharmaceutical company other than Mylan to enter the market with an authorized generic version of Colcrys®.

57. Between 2013 and today, Takeda has brought nine other cases against generic drug manufacturers who were seeking approval to manufacture, use, offer for sale, sell in and import into the United States a colchicine product that Takeda asserts is a generic copy of Colcrys® prior to the expiration of the Patents-in-Suit.

58. On information and belief, each of these cases settled upon the generic drug manufacturer's agreement not to enter the market with a generic colchicine product until a specified date that had not yet been reached as of the initiation of this litigation.

Mylan's Unlawful Interference with the Market for Generic Colchicine

59. On or about September 16, 2019, Mylan received approval from the FDA of the Mylan ANDA (i.e. ANDA No. 209470).

60. On information and belief, on or about November 25, 2019, Mylan launched the Mylan ANDA Product and entered the United States market. Specifically, Mylan began to manufacture, have manufactured, use, import, distribute, market, offer to sell, have sold, and/or

sell the Mylan ANDA Product in the United States. For example, the National Drug Code registry lists November 25, 2019, as the "Start Marketing Date" for the Mylan ANDA Product. A screenshot from the National Drug Code registry list is found at D.I. 20, Exhibit U.

61. On information and belief, Mylan has made substantial preparations for the commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan ANDA Product in the United States. Specifically, on information and belief, Mylan has begun manufacturing Mylan ANDA Product and/or arranging for its manufacture; storing the Mylan ANDA Product; importing the Mylan ANDA Product into the United States; taking other steps to develop an inventory of the Mylan ANDA Product; discussing the Mylan ANDA Product's upcoming availability with potential customers; and booking sales orders for the Mylan ANDA Product.

62. On information and belief, Mylan made these substantial preparations for the commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan ANDA Product in the United States in secrecy so as to prevent Par and Takeda from learning about these preparations until Mylan was prepared to launch is unauthorized generic colchicine.

63. On information and belief, Mylan has recently begun the process of notifying customers of the availability of the Mylan ANDA Product. On information and belief, Mylan has already contacted one or more of Par's distribution partners.

64. On information and belief, Mylan sold or offered for sale the Mylan ANDA Product to Par's distribution partners.

65. Upon information and belief, Mylan sold or offered for sale the Mylan ANDA Product to Par's distribution partners in willful disregard of the fact that said actions infringe the patents-in-suit and are in violation of Mylan's settlement agreement with Takeda. On

information and belief Mylan did so with the intent to interfere with, disrupt and damage Par's relationships with Par's distribution partners.

66. One or more of Par's distribution partners have cancelled their supply arrangements with Par and/or have approached Par to renegotiate the terms of their agreement(s) with Par regarding the supply of authorized generic colchicine. On information and belief, this was a direct and immediate result of Mylan's wrongful sale or offer for sale of the Mylan ANDA Product.

67. On information and belief, Mylan has expressly or implicitly made the false representation to Par's customers that it is authorized under the law to sell the Mylan ANDA Product, thereby damaging Par's market position and implying that Par's representations to its distribution partners were inaccurate or incomplete.

68. On information and belief, the Mylan ANDA Product has been sold and commercialized with its label containing instructions for use by doctors, pharmacists, other healthcare professionals, and patients.

69. As a result, on information and belief, the unauthorized and unlicensed launch of the Mylan ANDA Product has irreparably harmed and/or will irreparably harm Par by (a) injuring Par's relationships and goodwill with its distributors; (b) dramatically reducing the market share of Par's authorized generic product; and (c) causing the price of Par's colchicine products to immediately, substantially, and irrevocably decline.

Mylan's Infringement of the Patents-in-Suit

70. Takeda's FDA approved product label for Colcrys® teaches and encourages, *inter alia*, methods of using Colcrys® claimed in the Patents-in-Suit, including the use of colchicine

for prophylaxis and to treat gout or FMF when a patient is or is not taking another substance. (*See, e.g.*, D.I. 20, Ex. Y, Colcyrs® Label at Table 1).

71. The approved labeling for Colcrys® directs doctors, pharmacists, other healthcare professionals, and patients to practice the claimed methods of Takeda's Patents-in-Suit.

72. Under the Federal Food, Drug, and Cosmetic Act, drug products submitted to the FDA for approval via an ANDA are required to have the same labeling as the reference listed drug, here Colcrys®, except for changes required because of differences approved under a suitability petition (21 U.S.C. § 355(j)(2)(C); 21 C.F.R. § 314.93), because the generic drug product and reference listed drug are produced or distributed by different manufacturers (21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. §314.94(a)(8)(iv)), or because the ANDA applicant has made a section viii carve-out for one of the indications on the label of the reference listed drug.

73. On information and belief, the approved label for the Mylan ANDA Product (revised: 7/2019) is available online at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=85acf34c-06c6-40ea-95f4-060d5de99277, a copy of which is found at D.I. 20, Exhibit Z. On information and belief, Mylan's approved product is indicated for the prophylaxis and treatment of gout flares in adults and treatment of familial Mediterranean fever ("FMF") in adults and children 4 years or older.

74. On information and belief, the approved label for the Mylan ANDA Product directs doctors, pharmacists, other healthcare professionals, and patients to practice the following dosing information for prophylaxis of gout flares:

> The recommended dosage of colchicine tablets for prophylaxis of gout flares for adults and adolescents older than 16 years of age is 0.6 mg once or twice daily. The maximum recommended dose for prophylaxis of gout flares is 1.2 mg/day. An increase in gout flares may occur after initiation of uric acid-lowering therapy, including pegloticase, febuxostat and allopurinol, due to changing serum uric acid levels resulting in mobilization of urate from tissue deposits. Colchicine tablets are recommended upon

> initiation of gout flare prophylaxis with uric acid-lowering therapy. Prophylactic therapy may be beneficial for at least the first six months of uric acid-lowering therapy.

(D.I. 20, Ex. Z, Mylan's Label at § 2.1). On information and belief, the approved label for the Mylan ANDA Product directs doctors, pharmacists, other healthcare professionals, and patients to practice the following dosing information for the treatment of gout flares:

> The recommended dose of colchicine tablets for treatment of a gout flare is 1.2 mg (two tablets) at the first sign of the flare followed by 0.6 mg (one tablet) one hour later. Higher doses have not been found to be more effective. The maximum recommended dose for treatment of gout flares is 1.8 mg over a one-hour period. Colchicine tablets may be administered for treatment of a gout flare during prophylaxis at doses not to exceed 1.2 mg (two tablets) at the first sign of the flare followed by 0.6 mg (one tablet) one hour later. Wait 12 hours and then resume the prophylactic dose.

(D.I. 20, Ex. Z, Mylan's Label at § 2.1). On information and belief, the approved label for the Mylan ANDA Product directs doctors, pharmacists, other healthcare professionals, and patients to practice the claimed methods of Takeda's Acute Gout Flare Patents. For example, claim 1 of the '647 patent recites:

> A method of treating a patient having an acute gouty arthritis attack with colchicine consisting of administering 1.2 mg oral colchicine to a human patient having an acute gouty arthritis attack at the onset of the acute gouty arthritis attack, followed by 0.6 mg oral colchicine one hour later.

(D.I. 20, Ex. L at claim 1).

75. On information and belief, the approved label for the Mylan ANDA Product directs doctors, pharmacists, other healthcare professionals, and patients to practice the following dosing information for FMF:

> The recommended dosage of colchicine tablets for FMF in adults is 1.2 mg to 2.4 mg daily. Colchicine tablets should be increased as needed to control disease and as tolerated in increments of 0.3 mg/day to a maximum recommended daily dose. If intolerable side effects develop, the dose should be decreased in increments of 0.3 mg/day. The total daily colchicine tablets dose may be administered in one to two divided doses.

(D.I. 20, Ex. Z, Mylan's Label at § 2.2). Additionally, on information and belief, the approved label for the Mylan ANDA Product directs doctors, pharmacists, other healthcare professionals, and patients to practice to practice the following dosing information for pediatric patients:

> The recommended dosage of colchicine tablets for FMF in pediatric patients 4 years of age and older is based on age. The following daily doses may be given as a single or divided dose twice daily:
>
> Children 4 to 6 years: 0.3 mg to 1.8 mg daily
>
> Children 6 to 12 years: 0.9 mg to 1.8 mg daily
>
> Adolescents older than 12 years: 1.2 mg to 2.4 mg daily

(D.I. 20, Ex. Z, Mylan's Label at § 2.3).

76. On information and belief, the approved label for the Mylan ANDA Product directs doctors, pharmacists, other healthcare professionals, and patients to practice the claimed methods of Takeda's DDI Patents. the Mylan ANDA Product labeling states that "[c]o-administration of colchicine tablets with drugs known to inhibit CYP3A4 and/or P- glycoprotein (P-gp) increases the risk of colchicine-induced toxic effects (*Table 1*). If patients are taking or have recently completed treatment with drugs listed in Table 1 within the prior 14 days, the dose adjustments are as shown on the table below *[see DRUG INTERACTIONS (7)]*." (D.I. 20, Ex. Z, Mylan's Label at § 2.4; *see also id.* § 7 ("Table 1 provides recommendations for strong and moderate CYP3A4 inhibitors and P-gp inhibitors.")). Table 1 is reproduced *in part* below:

Table 1. Colchicine Tablets Dose Adjustment for Coadministration with Interacting Drugs if no Alternative Available*

Strong CYP3A4 Inhibitors†							
		Gout Flares				**FMF**	
		Prophylaxis of Gout Flares		**Treatment of Gout Flares**			
Drug	**Noted or Anticipated Outcome**	**Original Intended Dosage**	**Adjusted Dose**	**Original Intended Dosage**	**Adjusted Dose**	**Original Intended Dosage**	**Adjusted Dose**
Atazanavir Clarithromycin Darunavir/ Ritonavir‡ Indinavir Itraconazole Ketoconazole Lopinavir/ Ritonavir‡ Nefazodone Nelfinavir Ritonavir Saquinavir Telithromycin Tipranavir/ Ritonavir‡	Significant increase in colchicine plasma levels*; fatal colchicine toxicity has been reported with clarithromycin, a strong CYP3A4 inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other strong CYP3A4 inhibitors	0.6 mg twice a day 0.6 mg once a day	0.3 mg once a day 0.3 mg once every other day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 mg to 2.4 mg	Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)
Moderate CYP3A4 Inhibitors							
		Gout Flares				**FMF**	
		Prophylaxis of Gout Flares		**Treatment of Gout Flares**			
Drug	**Note or Anticipated Outcome**	**Original Intended Dosage**	**Adjusted Dosage**	**Original Intended Dosage**	**Adjusted Dosage**	**Original Intended Dosage**	**Adjusted Dosage**
Amprenavir‡ Aprepitant Diltiazem Erythromycin Fluconazole Fosamprenavir‡(pro-drug of Amprenavir) Grapefruit juice Verapamil	Significant increase in colchicine plasma concentration is anticipated. Neuromuscular toxicity has been reported with diltiazem and verapamil interactions.	0.6 mg twice a day 0.6 mg once a day	0.3 mg twice a day or 0.6 mg once a day 0.3 mg once a day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	1.2 mg (2 tablets) x 1 dose. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 mg to 2.4 mg	Maximum daily dose of 1.2 mg (may be given as 0.6 mg twice a day)

(D.I. 20, Ex. Z, Mylan's Label at Table 1).

77. On information and belief, the approved label for the Mylan ANDA Product directs doctors, pharmacists, other healthcare professionals, and patients to practice dose

adjustments for colchicine when co-administered with ketoconazole, verapamil, ritonavir, clarithromycin, and other drugs. These dose adjustments are disclosed and claimed in Takeda's DDI Patents. For example, claim 1 of the '298 patent recites the following:

> 1. A method of using colchicine for the treatment of Familial Mediterranean Fever in a human adult or child > 12 years of age in need of treatment thereof, said method comprising:
>
> orally administering a reduced colchicine dosage amount to the human adult or child > 12 years of age in need of treatment for Familial Mediterranean Fever who is concomitantly receiving administration of clarithromycin within 1 to 2 days of oral administration of colchicine,
>
> wherein the reduced colchicine dosage amount is reduced compared to a daily dosage amount to be administered in the absence of concomitant clarithromycin,
>
> wherein the daily dosage amount to be administered in the absence of concomitant clarithromycin is a maximum of 2.4 mg per day, and wherein the reduced colchicine dosage amount is a maximum of 0.6 mg per day.

(D.I. 20, Ex. E, claim 1). The dose adjustment table in the colchicine tablets provides that the usual intended dose of colchicine for FMF is a maximum of 2.4 mg. When colchicine is used with a strong CYP3A4 inhibitor such as clarithromycin, the colchicine tablets teaches that it should be adjusted from 2.4 mg per day to a reduced colchicine dosage of 0.6 mg per day (which may be given as 0.3 mg twice per day).

78. On information and belief, the approved label for the Mylan ANDA Product contains a Table 6, which describes doses of co-administered, such as ketoconazole, verapamil, ritonavir, clarithromycin, and others.

79. Accordingly, on information and belief, the approved label for the Mylan ANDA Product, like the labeling for Colcrys®, directs doctors, pharmacists, other healthcare professionals, and patients to practice the claimed methods of Takeda's Patents-in-Suit. (*See, e.g.*, D.I. 20, Ex. Z, Mylan's Label).

80. On information and belief, Mylan has and/or will induce others to infringe one or more claims of the Patents-in-Suit. Specifically, Mylan's label explicitly instructs doctors, pharmacists, other healthcare professionals, and patients to administer the Mylan ANDA Product according to methods claimed in one or more claims of the Patents-in-Suit. Such inducement is undertaken by Mylan with full awareness of all of the Patents-in-Suit, each of which was asserted by Takeda in *Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharmaceuticals Inc.*, C.A. No. 16-987-RGA (D. Del.). Such inducement is undertaken by Mylan, on information and belief, with full awareness and intent that Mylan's actions and the actions of the induced persons would infringe the Patents-in-Suit.

81. On information and belief, the Mylan ANDA Product has been or will be administered for the prophylaxis and treatment of acute gout flares and for the treatment of FMF.

82. On information and belief, Mylan's label demonstrates Mylan's specific intent that a doctor, pharmacist, other healthcare professional, or patient administer the Mylan ANDA Product according to the instructions on Mylan's labeling regarding treatment of acute gout flares and thus has and/or will directly infringe one or more claims of the Acute Gout Flare Patents.

83. On information and belief, Doctors, pharmacists, other healthcare professionals, and patients will administer the Mylan ANDA Product according to the instructions on Mylan's labeling regarding the treatment of acute gout flares and thus has and/or will thus infringe one or more claims of the Acute Gout Flare Patents.

84. On information and belief, Mylan's label demonstrates Mylan's specific intent that, when concomitant administration is necessary or desirable, a doctor, pharmacist, other healthcare professional, or patient administer the Mylan ANDA Product according to the

instructions on Mylan's labeling regarding dose reduction during concomitant administration and thus directly infringe one or more of claims of the DDI Patents.

85. On information and belief, Mylan will contribute or has contributed to the infringement of the Patents-in-Suit by offering to sell, selling, or distributing within the United States or importing into the United States the Mylan ANDA Product, knowing the same to be especially made for use in infringement of the Patents-in-Suit and not a staple article or commodity of commerce suitable for substantial noninfringing use. Mylan's infringement, including its contributory infringement, is described in further detail in Takeda's Complaint filed as D.I. 1 in C.A. No. 16-987-RGA, which is incorporated by reference herein.

86. On information and belief, some gout and FMF patients will undergo concomitant treatment with colchicine for gout and FMF and ketoconazole for a fungal infection.

87. On information and belief, some gout and FMF patients will undergo concomitant treatment with colchicine for gout and FMF and ritonavir for HIV or other viral infections.

88. On information and belief, some gout and FMF patients will undergo concomitant treatment with colchicine for gout and FMF and clarithromycin for bacterial infections, including *H. pylori*.

89. On information and belief, some gout patients will undergo concomitant treatment with colchicine for the treatment and/or prevention of acute gout flares and verapamil for hypertension, angina pectoris, cardia arrhythmia, and/or other disorders.

90. On information and belief, patients concomitantly taking ketoconazole, ritonavir, and/or clarithromycin with colchicine will be prescribed the Mylan ANDA Product according to the instructions on Mylan's labeling regarding dose reductions in accordance with Takeda's DDI

Patents by doctors or other healthcare professionals. Such doctors, healthcare professionals, and patients thus has and/or will directly infringe one or more of claims of the DDI Patents.

COUNT I FOR TORTIOUS INTERFERENCE WITH CONTRACTUAL RELATIONS

91. The allegations of paragraphs 1-90 are realleged and incorporated herein by reference.

92. Mylan does not have the legal right to manufacture, sell and/or offer for sale the Mylan ANDA Product because doing so would infringe the patents-in-suit and further because doing so is in violation of Mylan's agreement(s) with Takeda.

93. Mylan was and is aware of Par's license agreement with Takeda, which provides that Par is the sole authorized distributor of generic colchicine.

94. Mylan was and is aware that Par maintains contractual agreements with its distribution partners and that Par's authorized generic colchicine was and is sold to Par's distribution partners subject to these contractual agreements.

95. On information and belief, Mylan informed one or more of Par's distribution partners that Mylan had launched and/or would be launching the Mylan ANDA Product.

96. On information and belief, Mylan falsely informed one or more of Par's distribution partners that Mylan had the legal right to manufacture, sell and/or offer for sale the Mylan ANDA Product.

97. On information and belief, Mylan sold and/or offered for sale the Mylan ANDA Product to one or more of Par's distribution partners.

98. Mylan intentionally made these statements and performed these actions with knowledge and intent that its actions would interfere with Par's contracts and relationships with Par's distribution partners.

99. On information and belief, Mylan made preparations for its unlawful product launch in secrecy, to avoid Par learning of Mylan's intentions and to prevent Par from taking earlier action to prevent Mylan from damaging Par's relationships with its distribution partners.

100. Mylan made these statements and performed these actions without justification and in willful disregard for the fact that Mylan has no legal right to manufacture, sell and/or offer for sale (or otherwise distribute) the Mylan ANDA Product.

101. Mylan's statements and actions interfered with (and were intended by Mylan to interfere with) Par's execution of its agreements with Par's distribution partners and Par's enjoyment of the benefit of those agreements.

102. Mylan's statements and actions interfered with (and were intended by Mylan to interfere with) Par's relationships with its distribution partners and the goodwill Par had generated with such partners.

103. On information and belief, one or more of Par's distribution partners have altered or limited their relationships with Par as a direct result of Mylan's interference.

104. Mylan's statements and actions interfered with Par's execution of its agreements with Takeda and Par's enjoyment of the benefit of those agreements.

105. Mylan's statements and actions were highly damaging to Par and caused Par to lose substantial revenue.

106. As a direct and proximate result of Mylan's actions, Par has suffered, and continues to suffer, damages in an amount to be proven at trial, but in excess of the jurisdictional minimum of this Court.

COUNT II FOR UNFAIR COMPETITION

107. The allegations of paragraphs 1-106 are realleged and incorporated herein by reference.

108. Par, as the sole supplier of an authorized generic colchicine product, had and has a reasonable expectancy of entering a valid business relationship with pharmaceutical distributors.

109. On information and belief, Mylan has contacted one or more of Par's current and/or prospective distribution partners to inform them that Mylan had launched and/or would be launching the Mylan ANDA Product.

110. On information and belief, Mylan falsely informed Par's current and/or prospective distribution partners that Mylan had the legal right to manufacture, sell and/or offer for sale the Mylan ANDA Product.

111. On information and belief, Mylan made its preparations to make these false representations in secrecy, to avoid Par learning of Mylan's intentions and to prevent Par from taking earlier action to prevent them.

112. On information and belief, Mylan sold and/or offered for sale the Mylan ANDA Product to one or more of Par's current and/or prospective distribution partners.

113. Mylan made these statements and performed these actions without justification and in willful disregard for the fact that Mylan has no legal right to manufacture, sell and/or offer for sale (or otherwise distribute) the Mylan ANDA Product.

114. Mylan's statements and actions wrongfully interfered with Par's legitimate expectancy, as the sole authorized supplier of generic colchicine, of entering into contracts with these prospective distribution partners or of continuing or expanding its business relationships with its existing customers.

115. Mylan's statements and actions were highly damaging to Par and prevented Par from legitimately earning substantial revenue.

116. As a direct and proximate result of Mylan's actions, Par has suffered, and continues to suffer, damages in an amount to be proven at trial, but in excess of the jurisdictional minimum of this Court.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 7,601,758 BY MYLAN

117. The allegations of paragraphs 1-116 are realleged and incorporated herein by reference.

118. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the '758 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '758 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

119. As a result of Mylan's infringement of the '758 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

120. Mylan's past and continuing infringement of the '758 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT IV FOR INFRINGEMENT OF U.S. PATENT NO. 7,619,004 BY MYLAN

121. The allegations of paragraphs 1-120 are realleged and incorporated herein by reference.

122. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the '004 patent and without license or authorization from Takeda, Mylan has

infringed one or more claims of the ’004 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

123. As a result of Mylan’s infringement of the ’004 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

124. Mylan’s past and continuing infringement of the ’004 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan’s infringement is enjoined by this Court.

COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 7,820,681 BY MYLAN

125. The allegations of paragraphs 1-124 are realleged and incorporated herein by reference.

126. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the ’681 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’681 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

127. As a result of Mylan’s infringement of the ’681 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

128. Mylan’s past and continuing infringement of the ’681 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan’s infringement is enjoined by this Court.

COUNT VI FOR INFRINGEMENT OF U.S. PATENT NO. 7,906,519 BY MYLAN

129. The allegations of paragraphs 1-128 are realleged and incorporated herein by reference.

130. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the '519 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '519 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

131. As a result of Mylan's infringement of the '519 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

132. Mylan's past and continuing infringement of the '519 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT VII FOR INFRINGEMENT OF U.S. PATENT NO. 7,915,269 BY MYLAN

133. The allegations of paragraphs 1-132 are realleged and incorporated herein by reference.

134. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the '269 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '269 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

135. As a result of Mylan's infringement of the '269 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

136. Mylan's past and continuing infringement of the '269 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT VIII FOR INFRINGEMENT OF U.S. PATENT NO. 7,935,731 BY MYLAN

137. The allegations of paragraphs 1-136 are realleged and incorporated herein by reference.

138. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the '731 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '731 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

139. As a result of Mylan's infringement of the '731 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

140. Mylan's past and continuing infringement of the '731 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT IX FOR INFRINGEMENT OF U.S. PATENT NO. 7,964,647 BY MYLAN

141. The allegations of paragraphs 1-140 are realleged and incorporated herein by reference.

142. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the ’647 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’647 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

143. As a result of Mylan’s infringement of the ’647 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

144. Mylan’s past and continuing infringement of the ’647 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan’s infringement is enjoined by this Court.

COUNT X FOR INFRINGEMENT OF U.S. PATENT NO. 7,964,648 BY MYLAN

145. The allegations of paragraphs 1-144 are realleged and incorporated herein by reference.

146. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the ’648 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’648 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

147. As a result of Mylan’s infringement of the ’648 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

148. Mylan's past and continuing infringement of the '648 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT XI FOR INFRINGEMENT OF U.S. PATENT NO. 7,981,938 BY MYLAN

149. The allegations of paragraphs 1-148 are realleged and incorporated herein by reference.

150. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the '938 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '938 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

151. As a result of Mylan's infringement of the '938 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

152. Mylan's past and continuing infringement of the '938 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT XII FOR INFRINGEMENT OF U.S. PATENT NO. 8,093,296 BY MYLAN

153. The allegations of paragraphs 1-152 are realleged and incorporated herein by reference.

154. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the '296 patent and without license or authorization from Takeda, Mylan has

infringed one or more claims of the ’296 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

155. As a result of Mylan’s infringement of the ’2968 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

156. Mylan’s past and continuing infringement of the ’296 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan’s infringement is enjoined by this Court.

COUNT XIII FOR INFRINGEMENT OF U.S. PATENT NO. 8,093,297 BY MYLAN

157. The allegations of paragraphs 1-156 are realleged and incorporated herein by reference.

158. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the ’297 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’297 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

159. As a result of Mylan’s infringement of the ’297 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

160. Mylan’s past and continuing infringement of the ’297 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan’s infringement is enjoined by this Court.

COUNT XIV FOR INFRINGEMENT OF U.S. PATENT NO. 8,093,298 BY MYLAN

161. The allegations of paragraphs 1-160 are realleged and incorporated herein by reference.

162. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the '298 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '298 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

163. As a result of Mylan's infringement of the '298 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

164. Mylan's past and continuing infringement of the '298 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT XV FOR INFRINGEMENT OF U.S. PATENT NO. 8,097,655 BY MYLAN

165. The allegations of paragraphs 1-164 are realleged and incorporated herein by reference.

166. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the '655 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '655 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

167. As a result of Mylan's infringement of the '655 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

168. Mylan's past and continuing infringement of the '655 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT XVI FOR INFRINGEMENT OF U.S. PATENT NO. 8,415,395 BY MYLAN

169. The allegations of paragraphs 1-168 are realleged and incorporated herein by reference.

170. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the '395 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '395 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

171. As a result of Mylan's infringement of the '395 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

172. Mylan's past and continuing infringement of the '395 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT XVII FOR INFRINGEMENT OF U.S. PATENT NO. 8,415,396 BY MYLAN

173. The allegations of paragraphs 1-172 are realleged and incorporated herein by reference.

174. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the '396 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '396 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

175. As a result of Mylan's infringement of the '396 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

176. Mylan's past and continuing infringement of the '396 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT XVIII FOR INFRINGEMENT OF U.S. PATENT NO. 8,440,721 BY MYLAN

177. The allegations of paragraphs 1-176 are realleged and incorporated herein by reference.

178. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the '721 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '721 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

179. As a result of Mylan's infringement of the '721 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

180. Mylan's past and continuing infringement of the '721 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT XIX FOR INFRINGEMENT OF U.S. PATENT NO. 8,440,722 BY MYLAN

181. The allegations of paragraphs 1-180 are realleged and incorporated herein by reference.

182. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling of the Mylan ANDA Product prior to the expiration of the '722 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '722 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

183. As a result of Mylan's infringement of the '722 patent, Par has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

184. Mylan's past and continuing infringement of the '722 patent have caused, are causing, and/or will cause Par to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

DEMAND FOR JURY TRIAL

Par demands a jury trial on all claims, damages, and all other issues that are triable to a jury.

PRAYER FOR RELIEF

WHEREFORE, Par respectfully requests the following relief:

a. a judgment that Mylan's making, using, offering to sell, selling, marketing, distributing, or importing of the Mylan ANDA Product prior to the expiration of the patents-in-

suit will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the patents-in-suit;

b. a judgment that Mylan has tortiously interfered with Par's contractual relationships with its customers and/or prospective contractual relationship, and that Mylan has engaged in unfair competition;

c. an entry of preliminary and permanent injunctive relief enjoining and restraining Mylan and its affiliates, subsidiaries, directors, employees, agents, representatives, licensees, successors, assigns, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from further infringement of the Patents-in-Suit;

d. an award of Par's damages or other monetary relief to compensate Par if Defendant engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of the Mylan ANDA Product, or any product or compound the use of which infringes the patents-in-suit, or the inducement or contribution of the foregoing, prior to the expiration of the patents-in-suit in accordance with 35 U.S.C. § 271(e)(4)(C);

e. an award of Par's damages or other monetary relief to compensate Par for the damages caused by Mylan's tortious interference and unfair competition;

f. a judgment and declaration that Mylan's infringement of the Patent-in-Suit has been willful and deliberate, and for an award to Par of treble damages pursuant to 35 U.S.C. § 284;

g. a judgment that this is an exceptional case and awarding Par its attorneys' fees under 35 U.S.C. § 285;

h. an award of pre- and post-judgment interest, and the taxation of all allowable costs against Mylan;

i. an award of any further and additional relief to Par as this Court deems just and proper.

/s/ Karen E. Keller

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Dated: December 20, 2019

CERTIFICATE OF SERVICE

I, Karen E. Keller, hereby certify that on December 20, 2019, this document was served on the persons listed below in the manner indicated:

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